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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/610,935	07/06/00	WARD	B SGM 6934.1

EXAMINER	
SISSON, B	
ART UNIT	**PAPER NUMBER**
1655	7

DATE MAILED: 11/01/01

000321 HM22/1101
SENNIGER POWERS LEAVITT AND ROEDEL
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ST LOUIS MO 63102

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)

1- File Copy

Office Action Summary	Application No. 09/610,935	Applicant(s) WARD ET AL.	
	Examiner Bradley L Sisson	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) *23-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21 and 34-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 July 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-22, in Paper No. 6, received 01 August 2001 is acknowledged. The traversal is on the ground(s) that no undue burden would be placed against the Office be rejoinder of Groups II and II even though such may be distinct from one another. This is not found persuasive because while the inventions may share certain similar attributes, the searches are not necessarily coextensive, e.g., the invention of Group I would not require a search of class 204, subclass 456, however, Group II would require such a search. The performance of searches of additional classes would place an undue burden upon the Office.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 23-33 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.

3. This application contains claims 23-33 drawn to an invention nonelected with traverse in Paper No. 6. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-22 and 34-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

6. Claims 1-10 and 34-41 are drawn to a "composition suitable for formulation of an enzymatic reaction mixture, the composition comprising a reaction component essential for ex vivo non-polymerase enzymatic reaction." Upon review of the specification, it is noted at page 11, last paragraph, that the "enzyme" may include "those which modify or degrade proteins, lipids, carbohydrates, and metabolites, such as any kinase, protease, lipase, amylase, peroxidase, oxidase, oxygenase, and dehydrogenase. Enzymes that modify, cut, or synthesize nucleic acids are particularly suitable to be used with the present invention. Examples include any ligase, phosphodiesterase, DNase, exonuclease, RNase, phosphatase, kinase, terminal transferase, reverse transcriptase, restriction endonuclease, RNA polymerase, and DNA polymerase."

7. The specification has been found to set forth but two examples, the first of which is not applicable to the claimed composition (claims 1-10 and 31-34). Example 1, pages 18-30, "Identification and formulation of a Taq DNA polymerase with tracers and high density reagent," sets forth a preferred embodiment (see page 29), however, the composition formulated and utilized in the disclosed method was for an amplification reaction that did utilize a form of a polymerase, *i.e.*, Taq polymerase. It is noted with particularity that the claimed composition is "for an *ex vivo* non-polymerase enzymatic reaction."[1] In Example 1, it is disclosed that"[f]rom 180+ red dyes (absorbance max between 450 and 570 nm) (Table 1)" but 6 dyes (Bordeaux 1,

[1] Claim 1, preamble.

Acid Red 106, Acid Red 4, Acid Red 1, Amaranth, and Acid Violet 97) have been found to be compatible with Taq polymerase.

8. The only other example provided and the only example that exemplifies the invention of claims 1-10 and 34-41 is that of Example 2, pages 30-31, "Determination of the compatibility of a dye with restriction endonuclease." Upon inspection of the disclosure it is found that but one dye (Amaranth) has been studied and then with only a few restriction endonucleases. The specification does not provide an adequate written description of any other dyes that meet the function requirements of claims 1-22, and especially any of the other enzymes encompassed by claims 1-10 and 31-41. While the specification has been found to provide a listing of possible enzymes, the listing of enzymes does not rise to the level of identifying which dye(s) would be suitable for use with any of the myriad of enzymes encompassed by the claims. Clearly, applicant is seeking protection for a vast genus of compositions yet has provided but a few examples of that would be suitable with but one enzyme (Taq) and has evaluated but one dye with a few restriction endonucleases. Such limited disclosure does not satisfy the written description requirement of 35 USC 112, first paragraph. In support of this position, attention is directed to the decision in *In re Shokal*, 113 USPQ 283 (CCPA 1957) wherein is stated:

> It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. In re Soll, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; In re Wahlforss et al., 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.

***

> We are of the opinion that a genus containing such a large number of species cannot properly be identified by the mere recitation or reduction to practice of four or five of them. As was pointed out by the examiner, four species might be held to support a genus, if such genus is disclosed in clear language; but where those species must be relied on not only to illustrate the genus but to define what it is, the situation is otherwise.

Attention is also directed to the decision of *Vas-Cath Inc. v. Mahurkar* 19 USPQ2d 1111 (CAFC, 1991):

> This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 USC 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the "applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

7. As indicated above, the specification provides a description of but 6 dyes that are suitable with Taq polymerase and but one dye that is suitable with restriction endonucleases. The specification does not identify any other dye that is suitable with any other enzyme. Accordingly, the specification does not reasonably suggest that applicant was in possession of any other composition at the time of filing, *i.e.*, the complete genus of compositions claimed. While applicant has disclosed a method that could possibly be used for the identification of other dyes, such a teaching, while possibly being enabling for a method of identification of other dyes suitable for use with either *Taq* polymerase or restriction endonuclease, does not rise to the level of providing an adequate written description of those compositions which have the required properties. Accordingly, claims 1-22 and 34-41 are rejected under 35 USC 112, first paragraph,

as it relates to the failure of the specification to provide an adequate written description of the invention.

Response to arguments

8. At page 6 of the response attention is directed to non-identified pages of the specification as setting forth various enzymes that modify or degrade proteins as well as nucleic acid-modifying enzymes. Attention is also directed to Table 1 for providing a listing of tracers as well as to the method exemplified in Examples 1 and 2. Bridging to page 7 of the response, it is asserted that the number of examples provided is sufficiently representative of the genus and as such the rejection should be withdrawn.

9. The above argument has been fully considered and has not been found persuasive towards the withdrawal of the rejection. While agreement is seemingly reached in that the specification does provide a listing of enzymes as tracers, such are independent compounds. The claims, however, are drawn to compositions of which some of said compounds might be a part of. Rather than describing a representative number of encompassed species of compositions, the specification unfairly shifts the burden of written description from applicant to the public.

10. At page 7, bridging to page 10 of the response it is asserted that the specification does enable the claims, with attention being directed to Example 1 and 2 (pages 18-32 of the disclosure). Further argument is presented that a skilled art would know which enzymes to select in preparation of the composition and for use in the method.

9. The above argument has been fully considered and has not been found to be persuasive towards the withdrawal of the rejection. As set forth at pages 3-4 of this Office action: The specification has been found to set forth but two examples, the first of which is not applicable to

the claimed composition (claims 1-10 and 31-34). Example 1, pages 18-30, "Identification and formulation of a Taq DNA polymerase with tracers and high density reagent," sets forth a preferred embodiment (see page 29), however, the composition formulated and utilized in the disclosed method was for an amplification reaction that did utilize a form of a polymerase, *i.e.*, Taq polymerase. It is noted with particularity that the claimed composition is "for an *ex vivo* non-polymerase enzymatic reaction."[2] In Example 1, it is disclosed that"[f]rom 180+ red dyes (absorbance max between 450 and 570 nm) (Table 1)" but 6 dyes (Bordeaux 1, Acid Red 106, Acid Red 4, Acid Red 1, Amaranth, and Acid Violet 97) have been found to be compatible with Taq polymerase.

11. The only other example provided and the only example that exemplifies the invention of claims 1-10 and 34-41 is that of Example 2, pages 30-31, "Determination of the compatibility of a dye with restriction endonuclease." Upon inspection of the disclosure it is found that but one dye (Amaranth) has been studied and then with only a few restriction endonucleases. The specification does not provide an adequate written description of any other dyes that meet the function requirements of claims 1-22, and especially any of the other enzymes encompassed by claims 1-10 and 31-41. While the specification has been found to provide a listing of possible enzymes, the listing of enzymes does not rise to the level of identifying which dye(s) would be suitable for use with any of the myriad of enzymes encompassed by the claims. Clearly, applicant is seeking protection for a vast genus of compositions yet has provided but a few examples of that would be suitable with but one enzyme (Taq) and has evaluated but one dye

[2] Claim 1, preamble.

with a few restriction endonucleases. Such limited disclosure does not satisfy the written description requirement of 35 USC 112, first paragraph.

12. In view of the breadth of scope clamed, the limited guidance provided, the unpredictable nature of the art to which the claimed invention is directed, and in the absence of convincing evidence to the contrary, the claims are not enabled by the disclosure.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

B. L. Sisson

Bradley L Sisson
Primary Examiner
Art Unit 1655

bls
October 29, 2001